

1.4 PRODUCT INFORMATION.

1.4.1 Prescribing information (Summary of Product Characteristics).

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

Prometin-25 Tablets.

1.1 Strength:

Promethazine Hydrochloride 25mg.

1.2 Pharmaceutical Form:

Film Coated Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each Film coated tablet contains: Promethazine Hydrochloride BP 25mg and excipients in section 6.1

3. PHARMACEUTICAL FORM:

Film Coated Tablets.

Pink, circular, biconvex film coated tablets plain on both sides. Packed in blisters of 10 x 10's in unit box and 1000's in HDPE plastic container with literature insert.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

As symptomatic treatment for allergic conditions of the upper respiratory tract and skin including allergic rhinitis urticaria and anaphylactic reactions to drugs and foreign proteins. As an antiemetic

For short term use;

Treatment of insomnia in adults.

For short term use as a paediatric sedative

4.2 Posology and method of administration:

Route of administration: Oral.

Not recommended for children under 2 years.

As an antihistamine in allergy.

Children 2-5 years	5mL-15mL as a single dose or 5ml twice a day. Maximum daily dose 15mL. Prometin® Elixir is recommended for this age group.
Children 5-10years	10-25 mg as a single dose or 5-10 mg twice a day. Maximum daily dose 25 mg
Children over 10 years and adults (Including elderly)	25mg as a single dose or 10 mg twice a day. Increasing to a maximum of 25mg twice a day as required.

As an antiemetic

Children 2-5 years	5mL to be taken the night before the journey. To be repeated after 6 - 8 hours as required. Prometin® Elixir is recommended for this age group.
Children 5-10years	10mL or 10mg to be taken the night before the journey. To be repeated after 6 - 8 hours as required. Prometin Elixir or 10mg Tablets is recommended.
Children over 10 years and adults (Including elderly)	25mg to be taken the night before the journey. To be repeated after 6-8 hours as required.

As a paediatric sedative for short term use and for short term treatment of insomnia in adults:

Children 2-5 years	5mL-15mL as a single night time dose. Prometin® Elixir is recommended for this age group.
Children 5-10years	20-25 mg as a single night time dose.
Children over 10 years and adults (Including elderly)	25 or 50mg as a single night time dose.

4.3 Method of administration:

Prometin-25 Tablets are administered orally.

4.4 Contraindications:

Not be used in patients in coma or suffering from CNS depression of any cause.

Not be given to patients with a known hypersensitivity to promethazine or to any of the excipients. Contraindicated for use in children less than two years of age because of the potential for fatal respiratory depression.

Should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.5 Special warnings and precautions for use:

Prometin may thicken or dry lung secretions and impair expectoration. It should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis.

Use with care in patients with severe coronary artery disease, narrow angle glaucoma, epilepsy or hepatic and renal insufficiency. Caution should be exercised in patients with bladder neck or pyloro-duodenal obstruction.

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's syndrome. Promethazine may risk the warning signs of ototoxicity caused by ototoxic drugs e.g., salicylates. It may also delay the early diagnosis or intestinal obstruction or raised intracranial pressure through the suppression of vomiting.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine.

Prometin should not be used for longer than 7 days without seeking medical advice.

4.6 Paediatric population:

Not for use in children under the age of 2 years (see section 4.2)

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.

4.7 Interaction with other medicinal products and other forms of interaction:

Prometin will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic.

Alcohol should be avoided during treatment.

Promethazine may interfere with immunological urine pregnancy tests to produce false-positive or false- negative results.

Promethazine should be discontinued at least 72 hours before the start of skin tests as it may inhibit the cutaneous histamine response thus producing false-negative results.

4.8 Additional information on special populations:

No information has been provided on this section.

4.9 Paediatric Population:

Not for use in children under the age of 2 years (see section 4.2)

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.

4.10 Fertility, Pregnancy and Lactation:

Prometin should not be used in pregnancy unless the physician considers it essential. The use of Prometin is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonatal irritability and excitement.

4.11 Effects on ability to drive and use machines:

Because the duration of action may be up to 12 hours, patients should be advised that if they feel drowsy, they should not drive or operate heavy machinery.

4.12 Undesirable effects:

Side effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness, and disorientation. Anticholinergic side effects such as blurred vision, dry mouth and urinary retention occur occasionally.

Infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability.

The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine. Other side-effects include urticaria, rash, pruritus, anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported. Strong sunlight should be avoided during treatment.

4.13 Overdose:

Symptoms of severe overdosage are variable. They are characterized in children by various combinations of excitation, ataxia, incoordination, athetosis and hallucinations, while adults may become drowsy and lapse into coma. Convulsions may occur in both adults and children: coma or excitement may precede their occurrence. Cardiorespiratory depression is uncommon. If the

patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the antiemetic effect of promethazine; alternatively, gastric lavage may be used.

Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with diazepam or another suitable anticonvulsant.

The antiemetic effect of promethazine may be due to blockade of dopaminergic receptors in the Chemoreceptor Trigger Zone (CTZ) of the medulla.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic Group: Antihistamines for systemic use; Phenothiazine derivatives.

ATC code: R06AD02.

Promethazine is a phenothiazine antihistamine, antagonizing the central and peripheral effects of histamine mediated by histamine H1 receptors. The drug does not antagonize histamine at H2 receptors. Antihistamines competitively antagonize most of the smooth muscle stimulating actions of histamine on the H1 receptors of the gastrointestinal tract uterus, large blood vessels and bronchial muscle. Increased capillary permeability and oedema formation, flare and pruritus, resulting from actions of histamine on H1 receptors, are also effectively antagonized. Promethazine appears to act by blocking H1 receptor sites, preventing the action of histamine on the cell. Promethazine rapidly crosses the blood brain barrier and it is thought that the sedative effects of antihistamines are due to blockade of H1 receptors in the brain.

5.2 Pharmacokinetic properties:

Promethazine is distributed widely in the body. It enters the brain and crosses the placenta.

Promethazine is slowly excreted via urine and bile. Phenothiazine pass into the milk at low concentrations. Promethazine hydrochloride is readily absorbed from the gastrointestinal tract but-undergoes extensive first pass metabolism in the liver. With only 25% of the oral dose reaching the systemic circulation unchanged. After oral therapy therapeutic effects are identifiable at 15 – 30 minutes and peak plasma Concentrations at 2 to 3 hours. Estimates of terminal half-life in blood plasma have been quoted as 4-6 hours.

Its extensively plasma protein bound. It's eliminated mainly as metabolites, predominantly by the faecal (via biliary) route, with <1% of the parent compound and CA 10% as the sulfoxide metabolite being excreted in the urine over a 72-hour period.

5.3 Preclinical safety data:

No additional preclinical data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

- Microcrystalline Cellulose
- Pregelatinized Starch
- White Corn Starch (for paste)
- Purified Water
- Sodium Starch Glycolate
- Sodium Metabisulphate
- Sodium Lauryl Sulfate
- Purified Talc
- Magnesium Stearate
- Hydroxypropyl Methylcellulose (5 Cps)
- Titanium Dioxide
- Diethyl Phthalate
- Purified Talc
- Erythrosine Lake Colour
- Acetone
- Isopropyl Alcohol

6.2 Incompatibilities:

None Known.

6.3 Shelf life:

36 Months.

6.4 Special precautions for storage:

Store in a dry place, below 30°C.

Protect from light.

Keep all medicine out of reach of children.

6.5 Nature and contents of container:

Pink circular, biconvex film coated tablets plain on both sides. Packed in blisters of 10 x 10's in unit box and 1000's in HDPE plastic container with literature insert.

6.6 Special precautions for disposal and other handling:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES:**Marketing Authorization Holder:**

Company Name: Laboratory & Allied Limited.

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi

Country : Kenya

Telephone: +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com.

Manufacturing Site Address:

Company Name: Laboratory & Allied Limited.

Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi

Country : Kenya

Telephone: +254 20 8040306

Telefax : +254 20 8040309

E-Mail : info@laballied.com

8. MARKETING AUTHORIZATION NUMBER:

Kenya Reg No.: H92/010.

9. DATE OF FIRST REGISTRATION/ RENEWAL OF THE REGISTRATION:

Registration Date: 15/12/1994.

Renewal Date: To be retained annually.

10. DATE OF REVISION OF THE TEXT:

March, 2024.

11. DOSIMETRY (IF APPLICABLE)

Not Applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable.